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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/025,333

12/19/2001

Mahendra S. Rao

UT-0037

4765

7590

01/05/2005

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 01/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/025,333

Applicant(s)

RAO ET AL.

Examiner

Robert C. Hayes, Ph.D.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-34 is/are pending in the application.
- 4a) Of the above claim(s) 21-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 21-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/21/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restriction***

1. Applicant's election with traverse of Group II (claim 34) in Paper No: 11/04/04 is acknowledged. The traversal is on the ground(s) that "[s]earching for art relating to the cells of Groups I or II will clearly reveal any art relating to methods for isolation thereof as set forth in Groups III and IV, respectively or cells derived therefrom as set forth in Group V", and that "the application is a continuation application of U.S. Patent Application Serial No. 08/852,744 and a search by the Examiner of the instant application of prior art relating to mammalian CNS neuroepithelial stem cells and mammalian CNS glial-restricted precursor cells was already performed. Thus, no serious burden is placed upon the Examiner by including all Groups, or at least Groups I and II, in the prosecution of this case. This is not found persuasive because the methods of Groups III, IV & V require different starting materials, etc. (e.g., co-cultures, antibodies, or motoneurons, protocols, etc.) not required in Group II. A serious burden further exists because of the different goals and method steps required for the claims of Groups III, IV & V, which are not required for examination of the products of Group II, and for the reasons previously made of record in Paper No: 20040930. In contrast, Applicants' arguments are persuasive for re-joining Groups I (claim 34) and II (claim 33). However, the remaining restriction requirement is still deemed proper and is therefore made FINAL.

Claims 21-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No: 10/04/04.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33 & 34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 & 15, respectively, of U.S. Patent No. 6,361,996 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the sole difference between the instant claims and that claimed in '996 is the broadening of that claimed to the generic recitation of "mammalian... cells", versus "rat... cells" as patented in '996.

It is also suggested that line 2 of claim 34 be amended to "derived from [a] the neural tube...", in order to be more grammatically consistent with claim 33.

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Johe et al. U.S. Patent 5,753,506.

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-although Johe et al describe a "homogeneous population of rapidly dividing cells expressing nestin...characteristic for CNS precursor cells. Less than 1% of the cells [alternatively] expressed the astroglial marker GFAP or the oligodendroglial markers, O4 and GalC." (col. 13, lines 34-39). Therefore, Johe's "homogeneous population of... CNS stem cells that can be differentiated into neurons, oligodendrocytes, and astrocytes..." (col. 12, lines 29-34) are not a "pure, homogeneous population of mammalian neuro-epithelial stem cells...", as currently claimed, due to the presence of other differentiated cell types in Johe's otherwise homogeneous population of precursor cells. Additionally, Johe disclose that "[n]o simple antigenic marker is available which uniquely identifies multipotential stem cells from other precursors in vitro..." (col. 13, lines 59-62). Accordingly, Johe's homogeneous population of cells contain other "undifferentiated" precursor cells (e.g., col. 20, lines 40-42), such as the glial-restricted precursor cells of claim 34; thereby, distinguishing the instant inventions from that taught by Johe et al.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.
December 28, 2004

ROBERT C. HAYES, PH.D.
PATENT EXAMINER